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Wielding Organizational Influence in Health Care

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FROM THE EDITOR IN CHIEF

Oscaring *Parasite*

Audiey C. Kao, MD, PhD

ENG | ESP | 中文

A Chinese man in tattered clothing and a snake-like ponytail stands on a pedestal in a harbor. The words "filth," "immorality," "diseases," and "ruin to white labor" radiate from his head. This 1881 reimagination of the Statue of Liberty by cartoonist George Frederick Keller captured the widespread anti-Chinese fear and bigotry of the time.[1] Fueled by ignorance and racism, the Chinese Exclusion Act of 1882 became the first law in US history to restrict the immigration of people of a specific racial or ethnic group.[2] It was not until 1943 that exclusionary laws against Chinese immigrants were repealed because the United States wanted China as an ally in its war against Japan.[2]

With arrival of the novel coronavirus disease (COVID-19), fear of and racism against individuals who "look Chinese" have reemerged. Fewer customers are visiting businesses in US Chinatowns; Asians and Asian Americans have been berated and attacked in subways or questioned and refused service at hotels[3]; and some people scamper away after a cough or sneeze from those who are ethnically profiled. This is not the first time an illness has sparked panic and xenophobia against a specific group of people.[4] Sadly, it likely won't be the last.

To date, nearly 3000 deaths have been attributed to COVID-19, most of which happened in China; no deaths have been reported in the United States.[5] For context, 290 000 to 650 000 people die annually from seasonal influenza worldwide every year,[6] and it's estimated that 16 000 to 41 000 people have already died from influenza in the United States this flu season.[7] As we investigate, track, and learn more about this novel coronavirus, relevant and accurate information needs to be disseminated to the public in a timely and effective manner. Health care professionals play essential roles in educating patients and communities, but education is not enough: just ask any physician who has failed to convince a patient to get an influenza vaccination.

In a world of character-limited posts and instantly shared videos, creating and disseminating information—whatever its quality—seems to be in the hands of everyone, and falsehoods online spread faster and farther and seem to penetrate more deeply and pervasively than truths.[8] To address this "infodemic," governments, industry, professions, and the media must work together to contain and counter mis- and disinformation about the novel coronavirus.[9] The World Health Organization is currently working with tech and social media titans to remove mis- and disinformation and direct us all to credible resources.[10] Enlisting Fortune 500 companies and other large-scale employers is another key part of this truth-telling strategy, as employers tend to be considered trusted sources of information by many members of the public.[11] Global callouts by leading scientists and public health experts have condemned conspiracy theories about origins of the novel coronavirus and are notably pushing back against the worst impulses of the human condition that mis- and disinformation campaigns viralize.[12]

Falsehoods sow division and undermine solidarity in particularly pernicious ways when human cooperation is critical. We cannot afford fear, lies, and hatred to spread faster than the coronavirus because, in our interconnected world, no individual or community is an island. As a coronavirus pandemic appears inevitable, our common resolve to combat a global health threat will no doubt be tested. During these times, we expect and need those in positions of authority to be guided by the best available science, to act with civility and empathy, and to demonstrate leadership that justifies public trust.

Never before had a non-English language film been awarded the Academy Award for best picture. The Oscar-winning film from South Korea poignantly titled *Parasite* reminds each of us that what makes us laugh, cry, love, and despair is what makes all of us human. As we reckon with the threat and uncertainty posed by the novel coronavirus in the months ahead, let us encourage, celebrate, and vindicate our shared humanity.

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FROM THE EDITOR

Organizational Ethics for US Health Care Today

Patrick S. Phelan

Since the foundations of medical ethics were laid in antiquity, the practice of medicine has evolved in tandem with the landscape of health care systems. Humanity's wealth of contemporary clinical knowledge is accompanied by profound complexity in our health care systems, where diverse types of organizations (eg, hospitals, insurance companies, government agencies, private health investment firms) play equally diverse roles in acquiring and mobilizing resources. The significance of this complexity for health care ethics has become a subject of increasing scholarly recognition and analysis. Indeed, the integration of clinical and business ethics has produced an amalgam known as "organizational ethics."[1]

The interplay among hierarchy, management, and policy in current health care systems suggests that an organizational ethics lens is indispensable for appraising ethical problems.[2] How should organizations maintain reasonable expectations of professional employees? How should they promote ethical conduct of their constituents? How should they foster public trust in science and practice? The contributions to this issue of the *AMA Journal of Ethics* address these and other timely concerns in modern health care systems and illustrate ways in which ethical questions are often inextricably bound with organizational constituents, cultures, and relationships.

A fundamental difference between organizational ethics and traditional health care ethics is scope: traditional ethics focuses on individuals and organizational ethics on collectives.[3] Relevant collectives in health care—including groups of clinicians, patients, nonclinical workers, administrators, and institutions themselves—have diverse and often overlapping memberships and interests that might conflict. Characterizing these collectives is a challenge: corporate organizations can be effective communities, and the aims of making profit and promoting public good can stem from a common purpose.[4]

Types of membership in health care collectives are multifarious; some groups exist by virtue of a common profession or place of work, others are voluntary associations providing a cohesive group identity (eg, labor unions). Where union membership is an option for physicians in training, affiliation might suggest to some physicians' ethically relevant and possibly conflicting interests and obligations, especially when collective action (eg, striking) is considered.[5]

Where clinicians are employees, organizational culture can be understood as expressing organizational values and establishing and enforcing organizational norms. Moreover, organizations' goals for ethical conduct can be taken to reflect individuals' particular ethical values.[6] Organizations can communicate and propagate these values through mission statements, and such values can then be used to justify organizational goals or leveraged to manipulate constituent attitudes.[7] For better or worse, organizations can establish employee responsibilities and norms of conduct as measures for ensuring compliance.

Notions of transparency and trust surround relationships between health care organizations and outsiders. Contributions to this issue also address when—or whether—greater transparency begets greater trust[8] and conflicts that can arise between a health care organization and an individual member.[9] Institutional transparency and conflicts of interest can affect patients and constituents' relationships—most importantly, those of clinicians and their patients.[10,11] Health care organizations' interests and their potential conflict with interests of others under their authority are of great ethical significance, as partiality can threaten fiduciary obligations clinicians owe to patients. Moreover, health care organizations' interests can differ significantly from those of entities external to health care (eg, private equity firms).[12]

Given uncertain futures for health care systems, we should expect organizational considerations to be central in designing and delivering health care services. We can look to this issue for guidance about ensuring reasonable expectations of clinicians,[13] responsibly navigating clinicians' collective negotiations with employers,[5] enabling justifiable adjudication of disciplinary action against organization members,[14] maintaining cultures that discourage misconduct,[15] sufficiently communicating and responsibly leveraging organizations' aims to promote shared decision making,[7] crafting solutions when there are few or no alternatives,[9] and maintaining good public relations to foster trust.[8]

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CASE AND COMMENTARY

How Should Commerce and Calling Be Balanced?

Richard Gunderman, MD, PhD

Abstract

Physicians and all health professionals need to find an appropriate balance between the interests of individual patients and their organization's bottom line. Corporatization in health care has complicated such efforts. More and more health professionals function as employees of health care organizations, some of which value leaders' and shareholders' interests over those of patients. When faced with such conflicts, physicians bear a responsibility to put patients first and to advocate for their profession.

Case

Dr D has just completed residency training and has decided to join a large practice near her family. When she was recruited, the practice was negotiating its acquisition by a private equity firm.[1] Shortly after beginning in the practice, Dr D learns from a colleague that the firm's existing network of urgent care centers around the state is staffed by physician assistants (PAs)[2] whose work physicians in the practice are expected to supervise.[3]

Dr D expresses concern about being "stretched too thin" when this supervisory role is added to her already full clinical schedule. She is also concerned about whether remote supervision would ensure sufficient understanding of what's going on with patients for her (or any other physician) to adequately supervise and assess whether and when PA colleagues' responses to patients are clinically appropriate. She is particularly worried about whether remote supervision is sufficient when PAs care for patients with multiple comorbidities in the firm's most remote locations. She wonders whether working for this practice is turning out to be far more distressing than she'd thought when she signed her contract. Frustrated, Dr D thinks, *Working for a company that tries to economize personnel at the expense of patients' quality of care is just what I was trying to avoid by coming to work here*.

Commentary

At the core of this case is an ontological question that each physician needs to revisit again and again: Is medicine primarily a business activity that happens to involve the care of patients, or is it a calling to care for patients that cannot afford to ignore sound business practices? Is it more accurate to say that physicians are health care "providers" and patients "consumers" of health care? Is their relationship fundamentally an economic one, or should patients be seen as vulnerable human beings whom physicians are called upon to serve for reasons that are professional, humane, and perhaps even sacred?

Professional Issues

Many questions can be raised about Dr D, her employer, and the difficult situation in which she finds herself. How deeply did Dr D inquire into the nature of her employer's business model, utilization of PAs, and evolving ownership, and how accurately did representatives of her employer describe the nature of her employment? As a practical matter, one of the most important steps prospective employees and employers can take to promote a fruitful and enduring relationship is to ensure that both parties to an employment contract understand one another's expectations and cultures. This seems not to have been the case here.

Of course, an even deeper issue is in play—the fact that Dr D is not only joining a practice but also becoming an employee. For much of US medical history, physicians enjoyed an ownership interest in their practices, which ensured that they bore some degree of control over how their practices were structured and operated day to day.[4] When a medical practice, a hospital, or a health system is acquired by a private equity firm or a publicly traded company, the loyalties of the people making business decisions and the loyalties of those to whom they answer are likely to be focused on rates of return on investment (ROI).[5] For the time being, providing health care offers a relatively high ROI (which explains why such firms have invested so heavily in it), but that could change. When it does, who will remain on hand to serve the welfare of patients and communities?

Another issue at play here is Dr D's responsibility to supervise other health professionals—in this case, PAs at remote sites. From the point of view of a profit-focused health care firm, the employment of physicians may be an inconvenient necessity required to satisfy accreditors, regulators, and payers. Such a firm might prefer, wherever possible, to shift patient care responsibilities to lower-cost health professionals, such as PAs, in order to boost ROI. On the other hand, physicians might not wish to locate or commute to remote sites, making it difficult to provide services to patients in

need. In theory, telehealth offers one solution to this challenge. When push comes to shove, however, a physician's judgment that patients are being placed at risk through poor supervision should prove determinative.

Protecting Patients

There are numerous ways that patient interests can be protected. One way would be through adequate staffing. An effective triage system might also address the problem by ensuring that complex patients with multiple comorbidities are seen by appropriately qualified health professionals. Still another means of addressing the problem would be to ensure that physicians are available in remote facilities. This option might require offering higher compensation or other benefits to make such postings sufficiently attractive, but in a practice that puts patient interests first, doing so should be understood as a necessary cost of doing business.

Of course, the PAs in this case also bear professional responsibilities. They should clearly understand their own scope of practice and their legal and ethical obligations to ensure that they enjoy adequate physician consultation and supervision. Dr D would be well advised to talk with them about the nature of their daily work and perhaps to visit them at their practice locations. What kinds of patients are they seeing, and what is the scope of decisions they make in caring for them? Would they like to see more physician engagement? It is quite possible that many PAs feel uneasy about exceeding their scope of practice and would like to see the organization develop a better system of collaboration between PAs and physicians.

Dr D also needs to speak with colleagues in medicine in and outside her firm. How do they regard their workload—both the patients they see firsthand and those whose care is provided by PAs under their supervision? Do they believe Dr D's concerns are largely unfounded and, if so, why? If they share her concerns, can they cite specific cases when patients suffered as a result of remote supervision? Do any of them have suggestions for how the situation could be rectified? Are there examples in the organization of PA-physician teams that appear to be functioning well together, and could their approaches offer lessons for the rest of the organization? By learning more about what her colleagues think, feel, and do, Dr D can approach the situation with deeper understanding.

Forcing Dr D to stretch herself too thin is not in anyone's best interest. An employer that enforces unrealistically high expectations for physician productivity is merely sowing the seeds of physician burnout, with accompanying higher rates of error and patient dissatisfaction.[6] Patients will

also suffer. Ultimately, even the employer will suffer, as physician recruitment and turnover deteriorate. Good physicians will not seek employment in poor-quality practices, and eroding physician quality will not work to any organization's advantage. An employer seeking to make a quick buck might judge such sacrifices tolerable, but no one with a long-term commitment to patients, health professionals, and the community could conscience such a practice.

Organizational Response

How the practice and its owners respond to the concerns of Dr D and others would offer deep insight into what kind of an organization it is. It might care very little for patients and health professionals, regarding them as mere commodities. Or it might be doing the best it can under difficult economic circumstances. Does the organization take the expression of Dr D's concerns seriously as a learning opportunity, attempting to adjust its practice model accordingly, or does it dismiss them out of hand? Does anyone in the organization engage with her in a personally responsible way, or is she met with handwaving and vague expressions of regret about "the system?" Does anyone seem to care about her capacity to practice medicine in a way she is proud of, or is she met with attempts to silence, isolate, and intimidate her?

Calling Over Commerce

We might think Dr D's concerns are novel and perhaps even unprecedented—the product of new health information technology, health care payment systems, and the corporatization of medicine. In fact, however, the underlying issues are as venerable as medicine itself. One of the finest voices of medicine's conscience, Sir William Osler, well captured the timeless nature of such concerns when he wrote, "Our fellow creatures cannot be dealt with as man deals with corn and coal; 'the human heart by which we live' must control our professional relations."[7] In other words, patients, families, communities, and the profession must never be treated as mere means of making money.

Osler warned physicians never to allow business considerations to trump the higher calling of compassion and hope.

> You are in this profession as a calling, not as a business; as a calling which exacts from you at every turn self-sacrifice, devotion, love and tenderness to your fellow-men. Once you get down to a purely business level, your influence is gone and the true light of your life is dimmed. You must work in the missionary spirit, with a breadth of charity that raises you far above the petty jealousies of life.[8]

As *professionals*, as opposed to *workers*, physicians should profess something—a dedication to purposes beyond money and self-enrichment. This loyalty implies, at least in some cases, a refusal to participate in—and even a mission to oppose—organizational policies and pressures that violate higher professional responsibilities. There are things a physician must never do, no matter how much an employer promises by way of reward or threatens in punishment. An employment contract is just that—a contract. But medicine is a covenant, a calling to a higher order that supersedes the business objectives of any particular health care organization.

Dr D's choices are multiple. First, she could simply resign, rejecting an approach to patient care that she would not conscience for her own loved ones. Second, she could remain in the organization as an advocate for patients, making the case as effectively as she can for an alternative approach that would better serve patients and health professionals and ultimately redound to the benefit of the organization. Third, whether she resigns or remains, she could make it her business to increase awareness of what she sees as unconscionable threats to patient safety and quality care. Assuming the role of whistleblower might get her fired, but it might also save lives.

Suppose a group of rich people buys a professional sports team and, brandishing financial penalties, termination, and even lawsuits, requires the team's players to start breaking the rules in order to win games. Would the players be obliged to accede to their bosses' demands and start cheating? I think not, and this conclusion remains equally valid regardless of whether employees can appeal to an arbitrator. The players should abide by what they know to be right. More broadly speaking, it is never wrong to do what is right, no matter how dire the consequences. Like athletes who refuse to cheat, physicians who refuse to allow ROI to trump the welfare of patients are always on the side of the angels.

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CASE AND COMMENTARY

What Should Physicians Consider Prior to Unionizing?

Danielle Howard, MD

Abstract

Physicians considering unionization face many practical, emotional, and moral obstacles. Even some who feel that a collective bargaining unit is necessary remain concerned that patient care could suffer if physicians unionize. This article discusses unionized physicians' moral obligations to patient populations and health care systems' share in this responsibility. It argues that unionization can be done ethically as long as union actions are focused on improving patient care.

Case

Dr Y has relocated to a new city to begin her internship. Resident physicians in Dr Y's training program recently voted to be represented by a labor union.[1,2] Membership is optional, but a common employment contract has been negotiated with the purpose of protecting the interests of all resident physicians, including those not paying membership dues. As Dr Y begins her postgraduate training, the union is negotiating terms of the organization's contracts with resident physicians for the first time since the program's establishment.

Dr Y has so far not made a decision about joining the union. Some senior resident physician peers have encouraged her to join the union,[3] emphasizing the need for professional solidarity and for everyone to contribute to prioritization of their common interests. Dr Y and others are hesitant to join the union in part because they wonder what exactly collective action might require of individual physicians and how it could affect their patients and careers. Short of an outright strike, union representatives have suggested that actions could include resident physicians' refusal to perform particular tasks, such as entering critical billing-relevant information into patients' health records. Dr Y considers that this action could be justifiable as long as

patients still get needed care.[4] Overall, however, she wonders whether she should join the union.[5]

Commentary

The right to unionize and strike was guaranteed under the Clayton Act[6] and the Norris-LaGuardia Act[7] and extended to physician employees under the National Labor Relations Act.[8] There are many advantages of physician unions, including collective bargaining for better working conditions, protection from legal action, and the ability to advocate for improved patient care. There is also a potential benefit to patients: one study of hospitals in California showed a 5.5% reduction in patient mortality in those with nursing unions.[9] Most importantly, unions provide physicians a measure of autonomy—something they frequently grant to patients and, with recent health care changes, often cede to their employers. Despite these benefits, relatively few physicians are members of unions, with only 11.4% of health care practitioners and technical workers reporting union membership in 2018.[10] This article discusses what physicians should consider prior to joining unions, ethical complexities of collective action and its consequences, and unionized physicians' and organizations' responsibilities for patient care.

Considerations in Union Membership

All physicians considering joining a labor union have many factors to consider. First, they must evaluate whether the union's objectives are in line with their values. Ironically, in order to fight for autonomy in clinical practice as union participants, physicians must sacrifice some of their individuality. Once physicians become members, actions taken by the union will reflect on them personally and could affect how they are viewed by their patients, peers, supervisors, and future employers (although their interactions with these groups might be affected by nonmembership as well). Patients, in particular, might feel that unionized physicians are acting unprofessionally or placing personal needs above their best interests, which can compromise the patient-physician relationship.[11] This is especially true if physicians are called upon to participate in collective action as a result of their union membership.

Resident physicians considering union membership face additional challenges. Although all unionized physicians contribute to union dues, the average resident has an income that is less than a third of, and works many more hours than, the average practicing attending physician.[12,13] Resident physicians are especially vulnerable to exploitation due to the MATCH contract, which assigns medical students to residencies, thereby removing their ability to bargain for wages and benefits prior to starting their jobs.[14]

Residents are also more at risk for exploitation due to their learner status and dependency on their supervisors for teaching, feedback, and guidance. Despite these challenges, residents might feel that unionization is necessary or decide to join a union in solidarity with their colleagues. They might also wish to avoid becoming "free riders" (as the House Officers Association at Michigan calls them) who benefit from union actions without contributing dues.[15]

Residents have led several physician strikes over the last 30 years,[16,17,18] likely in part because they do not have final decision-making power when it comes to patient interactions but must instead defer to their attending physicians. This subordinate role makes collective action on the part of residents ethically less complicated, as patient care continues despite resident absence.

Ethical Complexities of Collective Action

Collective action poses ethical complexities for physicians, who are among the few professionals bound by oath to those they serve. A 2015 survey found that 100% of responding medical schools had their students take an oath at least once during their 4 years of training, and a frequent theme of these oaths is that physicians should do everything possible for their patients.[19] This theme is reiterated by the American Medical Association's Principles of Medical Ethics, which states, "A physician shall, while caring for a patient, regard responsibility to the patient as paramount."[20] It is therefore not surprising that physicians feel sworn to value patient care over their own needs and, for this reason, avoid unionization. Unionized physicians might fear breaking their oath if and when collective action harms patients.

There are 2 problems with this thinking, however. The first is that collective action does not necessarily require striking, as physicians have other means of adjusting their workflow to affect their employer without rejecting all clinical duties. Examples of such adjustments include refusing to perform elective surgeries or neglecting documentation to prevent effective billing. Second, studies have found that, historically, physician strikes have not been harmful to patients, with one study finding that the 1976 Los Angeles County physician strike "was responsible for more deaths prevented than lives lost."[21]In the same vein, medical resident absences from emergency departments have been shown to improve or not to affect efficiency without increasing mortality.[22,23]

Nonetheless, if a group of physicians decides to employ collective action, there are legal and ethical ground rules to follow to ensure patient safety. The

National Labor Relations Act stipulates that physician unions must give employers a 10-day notice of "concerted refusal to work."[8] Physicians must also ensure that emergency care is still available to those who seek it and that patients who are already hospitalized continue to receive care. If unionized physicians feel that prolonged action is required, they must regularly evaluate the collective effect of their behavior on patient care. Patient safety is most physicians' priority, but physician strikes will almost always disadvantage patients in some way even if done safely.

The possible disadvantage to patients highlights the crux of the moral issue of physician strikes. In Immanuel Kant's *Groundwork for the Metaphysics of Morals*, one formulation of the categorical imperative is to "Act in such a way as to treat humanity, whether in your own person or in that of anyone else, always as an end and never merely as a means."[24] When patient care is leveraged by physicians during strikes, patients serve as a means to the union's ends. Unless physicians act to improve *everyone's* care, union action—if it jeopardizes the care of some hospitalized patients, for example—cannot be ethical. It is for this reason that, in the case of physicians looking to form a new union, the argument can be made that unionization should be used only as a last resort. Physician union members must be prepared to utilize collective action and accept its risks to patient care, but every effort should be made to avoid actions that risk harm to patients.

This ethical problem evaporates if physicians strike on behalf of patient care, thereby making patients an end as well as a means. There are several instances in which patient care influenced physicians' collective actions. One example is a resident strike in 1997 at Boston Medical College to demand translators for non-English speaking patients.[25] If other avenues of change have been exhausted, it is morally acceptable for physicians to unionize and employ collective action—including striking—as long as patients' best interests are their reason for doing so. Such collective action would not only mitigate ethical complexity but also garner support, and, historically, physician strikes have been more successful when they have strong support from both physician and patient populations.[16]

Institutional Responsibility

When discussing ethics, practicalities, and outcomes of physician unions, the focus is almost always entirely on physicians. Yet to place the weight of responsibility for patient care entirely on unionized clinicians is unjust, as Kant's reasoning applies to the employing organization as well (hereafter referred to as "the health system"). The health system benefits from

physicians providing patient care; if it then creates working conditions that its employed clinicians do not find sustainable, it violates the categorical imperative by using clinicians as a means to its end. The same can be said of patients, who are used as means to an end if the health system places restrictions on patient care for financial gain. When evaluating the ethics of physician unionization, it is important to realize that the health system has its own corporate social responsibility to both patients and physicians that is independent of physicians' commitment to patient care.[26] Physicians are expected to consider the effects that their unionization will have on the patient population because they have a responsibility to patient care. The health system shares equally in this responsibility.

Patients Come First

There are many competing factors for a physician to consider prior to unionization, but the overarching issue is ethical. Physicians can weigh the possible loss of identity against a sense of solidarity, improved wages and benefits against the price of union dues, and improved workplace satisfaction against damage to the patient-physician relationship; but, ultimately, they cannot morally unionize until they have exhausted all other means of negotiation. Unionization comes with at least a threat of collective action, and although collective action by physicians is not necessarily harmful, it poses an ethical issue if physicians are only acting in their own interests. Physicians must consider their responsibility to patients prior to unionizing and work with the health system to improve workplace conditions without threatening collective action. The health system must similarly consider its moral duty to patients and physicians and provide a positive environment for working and healing. Ultimately, responsibility for patient care lies with both parties, who can succeed only when each party prioritizes patient care.

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CASE AND COMMENTARY

How Should Organizations Respond to Repeated Noncompliance by Prominent Researchers?

Min-Fu Tsan, MD, PhD and Grace L. Tsan, OD

Abstract

This article considers a case in which a prominent researcher repeatedly made protocol deviations year after year while the institutional review board and university leadership failed to adequately address his continuing noncompliance. This article argues that, in addition to reporting this researcher's pattern of noncompliance to the Office for Human Research Protections, as required by federal regulations, the university should implement a remedial action plan.

Case

Dr E is a physician-researcher and leading expert in his field whose work brings in millions of dollars in grant funding for the university. He and his collaborators regularly publish in top scholarly journals and garner national media attention. Despite Dr E's team's productivity and success over the past 15 years, its protocols' record of compliance with human subjects protection regulations has never been perfect and has recently gotten spottier. Deviations from institutional review board (IRB)-approved protocols so far do not appear to have violated subjects' welfare or safety. And for each known past deviation,[1] the IRB notified Dr E, as principal investigator, whose team responded by submitting protocol modification requests[2] to the IRB, which were all approved. IRB members remain concerned about what has now become Dr E's team's persistent, years-long pattern of deviating from protocol and then needing reminding about federal regulatory compliance obligations.

The IRB's chair, Dr J, has grown frustrated over the years by failed attempts to solicit assistance from university leadership in motivating Dr E to comply with requirements without recurrent prompting. In a letter to the university's new provost, Dr A, and board of trustees,[3] Dr J stated, "Dr E's team's pattern of disregard for compliance with federal human subjects protections concerns

IRB committee members deeply. We feel obligated to recommend to the university leadership that current trends, which are well documented, should not continue to be tolerated out of respect for subjects' vulnerabilities and out of respect for IRB board members' volunteer service to the university."

When Dr J wrote similar letters in the past, members of university leadership were divided about how to respond. The majority emphasized the importance of Dr E's team's prominent contributions to the field and to the university and reminded the others that violations have been minor. A few agreed with Dr J that continued tolerance of Dr E's team's repeated deviations, though minor in the past, could be perceived as sanctioning more serious noncompliance in the future that could imperil subjects and the university's reputation. Others suggested that Dr E's team's pattern of protocol deviations could be seen as undermining the university IRB's authority and the integrity of federal human subjects regulatory processes—but not enough to interfere. Proponents of this latter view conceded that Dr E should comply without prompting, but they pointed out that his team has, in the end, always responded to the IRB's requests and that the IRB is doing what it needs to do. They continue to hold that there's no need for university leadership to intervene in how the organization functions with respect to human subjects research governance.

As a new provost, Dr A looks into the matter further. Federal human subjects research protections require reporting of "continuing noncompliance,"[4] but IRBs have discretion about how to interpret and report an investigator's pattern of minor noncompliance.[5] Nevertheless, Dr A finds that IRBs are charged with assessing and addressing issues of research protocol deviations on behalf of any organization that receives federal funds for human subjects research. Dr A considers how she should urge the university's leadership to respond.

Commentary

In this case, Dr E has been taking advantage of his status as a prominent researcher. In recognition of Dr E's prominent academic achievements and financial contributions to the university, the IRB considered Dr E to be so important as to be untouchable. While members of the university leadership differed in their opinions regarding the implications of Dr E's repeated noncompliance, they all agreed that there was no need for the university to intervene. In fact, some strongly believed that "there's no need for university leadership to intervene in how the organization functions with respect to human subjects research governance."

As the new provost, Dr A investigated the matter further and noted that federal regulations require reporting of continuing noncompliance[6] and that the IRB so far had not adequately addressed Dr E's pattern of protocol deviations on behalf of the university. Thus, it is particularly pertinent for Dr A to ask the question, "How should organizations respond to repeated noncompliance by prominent researchers?" In order to answer this question properly, one needs to understand our current system of protecting human subjects participating in research. We believe that the university should report Dr E's continuing noncompliance to the Office for Human Research Protections (OHRP), as required by federal regulations, and implement a remedial action plan to effectively prevent recurrence of protocol deviations.

Federal Human Subjects Protections

Since 1974, the Federal Policy for the Protection of Human Subjects, also known as the Common Rule after 1991, has relied on IRBs to review and approve human research protocols as well as to provide continued oversight to ensure that the rights and welfare of human subjects participating in research are protected.[6] Under this system, for many years research institutions delegated authority and responsibility for protecting human research subjects to their IRBs, often without providing sufficient financial and administrative support. As a result, IRBs were overworked and undersupported.[7]

A paradigm shift toward less reliance on IRBs for oversight occurred in the late 1990s and early 2000s when it became clear that IRB oversight alone was insufficient to protect human subjects participating in research. Two young volunteers, Jesse Gelsinger and Ellen Roche, who participated in phase one clinical trials out of altruism, died on September 17, 1999, and June 2, 2001, respectively, as a result of egregious noncompliance by the investigators and IRBs.[8,9,10] In addition, a number of major academic institutions' federally funded research programs were temporally suspended due to persistent, serious noncompliance with federal regulations.[8,11] Since that time, institutions conducting research involving human subjects have established operational frameworks, referred to as human research protection programs, to ensure that the rights and welfare of research participants are protected and to meet ethical and regulatory requirements that are essential for the protection of human subjects.[13,14] In addition to IRBs, investigators, institutions, sponsors of research, research volunteers, and the federal government share responsibilities for protecting human research subjects.[12]

Under the current system, ultimate responsibility for human subjects protections resides at the highest level of the institution. The institution must assume the leadership role in ensuring the integrity of its human research protection program by providing adequate resources and establishing ethics education programs and a culture of research excellence and transparency as well as by continuous monitoring and quality improvement through program accreditation.[12,13] The belief that "there's no need for university leadership to intervene in how the organization functions with respect to human subjects research governance" held by some members of the university leadership in this case is thus entirely inappropriate.

Recommendations for Scope of University Research Oversight Responsibilities

We propose that the following ethical criteria be used to consider the nature and scope of the university's responsibilities to various stakeholders in this case.

- Protecting the rights and welfare of human research subjects should be the university's highest priority;
- The university should take the lead role in ensuring the integrity of its human research protection program;
- Serious or continuing noncompliance should not be tolerated regardless of an investigator's seniority or level of research funding; and
- The university should take a proactive role in addressing issues of noncompliance that are beyond its IRB's capability to resolve.

In subsequent paragraphs, we will focus our discussion on the third and fourth criteria.

We suggest that the provost, Dr A, recommend to the university leadership reporting Dr E's continuing noncompliance to the OHRP, along with implementing a remedial action plan to prevent Dr E's protocol deviations from recurring, in line with the Guidance on Reporting Incidents to OHRP.[4] The remedial action plan should include a university-wide educational training for all investigators, including Dr E and his staff, regarding the importance of complying with IRB-approved research protocols and the consequences of protocol deviations. In addition, the university should assign or hire a research compliance officer to work with Dr E, his staff, and the IRB to ensure that all contemplated research activities that are outside of IRB-approved protocols are submitted to the IRB for review and approval prior to their

implementation, except when deviations from protocol are performed to eliminate apparent immediate hazards to a subject.[6]

Having a research compliance officer, part-time or full-time, to work with Dr E, his staff, and the IRB to prevent any protocol deviations from recurring demonstrates that the university leadership will take a proactive role in addressing issues of noncompliance that are beyond the IRB's capability to resolve. It is an investment by the university that is well justified in view of Dr E's prominent contributions to the field and the university.

Reporting Dr E's continuing noncompliance to the OHRP will give a strong message to:

- Dr E that repeated protocol deviations, even minor protocol violations that do not cause actual harms to human subjects, cannot be tolerated;
- The research community at large that serious noncompliance or continuing noncompliance will not be tolerated regardless of an investigator's seniority and level of research funding; and
- The IRB that it has failed to carry out its responsibility to inform the university leadership of Dr E's continuing noncompliance and report it to the OHRP as required by federal regulations, given that Dr E's continuing noncompliance was so obvious and well documented.[1,6]

One could argue that there is no need to report Dr E's repeated protocol deviations to the OHRP. Although the Common Rule requires that continuing noncompliance be reported, it does not explicitly define what constitutes continuing noncompliance.[4,6] It does permit IRBs some latitude in interpreting and determining whether the investigator's pattern of minor noncompliance constitutes continuing noncompliance. Since the IRB so far has not determined that Dr E's repeated protocol deviations year after year constitute continuing noncompliance and, moreover, these deviations have not resulted in actual harms to human subjects, it would be simpler if Dr A would just follow the previous university policy and decide not to intervene. However, whether to report continuing noncompliance is not entirely up to the IRB's discretion, especially in this case, in which the IRB's decision was unduly influenced by Dr E's prominent researcher status. If there is any doubt, either Dr A or the IRB chair, Dr J, should consult the OHRP for advice. The OHRP considers the following to be examples of continuing noncompliance:

- The principal investigator (PI) makes the same mistake repeatedly, especially after the IRB has informed the PI of the problem;
- The PI has multiple problems with noncompliance over a long period; and
- The PI has problems with multiple projects.[15]

One could also argue that there is no need to assign a research compliance officer to work with Dr E, his staff, and the IRB to prevent future protocol deviations from recurring, since the university could not possibly afford to have a research compliance officer work with each investigator who is repeatedly noncompliant. We agree that having a research compliance officer work with Dr E, his staff, and the IRB is a substantial, albeit temporary, investment on the part of the university. However, if Dr E continues to make protocol deviations after the educational training, there are few options open to the IRB and the university other than temporarily to suspend his research protocols, which we believe is one option that the university would not want to take. Our proposed approach offers the best chance to ensure that Dr E's protocol deviations would not recur. In view of Dr E's prominent contributions to the field and the university, this investment in a remedial action plan is well justified.

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HEALTH LAW

Which Legal Approaches Help Limit Harms to Patients From Clinicians' Conscience-Based Refusals?

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Abstract

This article canvasses laws protecting clinicians' conscience and focuses on dilemmas that occur when a clinician refuses to perform a procedure consistent with the standard of care. In particular, the article focuses on patients' experience with a conscientiously objecting clinician at a secular institution, where patients are least likely to expect conscience-based care restrictions. After reviewing existing laws that protect clinicians' conscience, the article discusses limited legal remedies available to patients.

Potential Sites of Conflict

Clinicians who object to providing care on the basis of "conscience" have never been more robustly protected than today by state legislatures and federal law. Although US law as well as professional ethics allows clinicians to deviate from professional norms and standards when their religious or moral beliefs conflict with a requested service,[1] the scope of legal remedies for patients harmed by these objections has shrunk as federal and state law has effectively insulated objecting clinicians from liability. This article outlines laws protecting clinician conscience and identifies questions that arise when a clinician refuses to perform a procedure consistent with the medical profession's standard of care. We focus on patients seeking care at secular institutions where patients are least likely to have notice that care they receive could be restricted based upon an individual clinician's refusal. As a result, patients may unknowingly receive substandard care from objecting physicians and even be harmed by their refusals. However, the legal remedies available to patients adversely affected by refusals are limited. We first discuss federal and state law governing refusals based on clinician conscience and then examine the remedies available to patients who suffer harm as a result of a physician's refusal.

Existing Laws Protecting Clinician Conscience

Over the past half century, Congress has passed multiple laws protecting clinicians who refuse to provide reproductive health care on the basis of conscience. Enacted in the 1970s, the Church Amendments prohibit any entity that receives public funding from discriminating against any "health care personnel" refusing to perform or assist in the performance of a sterilization or abortion procedure because it "would be contrary to his religious beliefs or moral convictions."[2] The Coates-Snowe Amendment prohibits federal, state, and local officials from discriminating against entities that receive federal financial assistance, including physician training programs, that refuse to provide training on abortion care, the abortion procedure itself, or referrals for abortions.[3] This prohibition extends to discrimination in licensing or accreditation decisions even if these services are generally required in neutral state policies, such that a religiously affiliated institution may be excused from providing—and an individual clinician from undergoing—training on abortion care.

In May 2019, the US Department of Health and Human Services (HHS) issued a final rule that expands the scope of conscience protections for health care entities and any "health care personnel" who refuse to "take an action that has a specific, reasonable, and articulable connection to furthering a procedure" to which the person or entity objects.[4] The regulation also includes protections for an objecting clinician's refusal to refer to nonobjecting clinicians.[5] The Trump administration has emphasized its commitment to protecting these rights through the creation of a new Conscience and Religious Freedom Division that was established to "restore federal enforcement of our nation's laws that protect the fundamental and unalienable rights of conscience and religious freedom."[6]

States, cities, and reproductive health advocates have initiated a multitude of lawsuits against HHS to overturn this new regulation. Three district courts in California, New York State, and Washington have ruled to enjoin the law.[7,8,9,10] However, there is political pressure on the administration to fight to maintain the rule all the way to the Supreme Court.[11,12] But even if these suits are successful, as discussed below, health care practitioners and programs will be protected by federal law from adverse employment action when refusing to provide care and, under many states' laws, they are even shielded from liability for harms caused by their actions.

The new regulation covers any procedure, health service program, or research activity.[4] Individual health care professionals and entities can refuse to provide care, even in emergency situations, if that care would conflict with their beliefs.[4] Additionally, health care professionals may refuse not only to perform an abortion but also to counsel on abortion or to refer an individual seeking an abortion to a willing clinician, and delays in the context of abortion care can lead to more invasive, risky procedures or eliminate the woman's right to choose if the delay takes her past the viability limit set by the Supreme Court.[13]

Moreover, the new regulation protects the conscience of religious institutions such as the Catholic hospitals that serve 1 in 7 patients.[14] For example, a woman undergoing a cesarean delivery will be unable to obtain a concurrent tubal ligation at a Catholic hospital and will be required to seek a second surgery at another provider, which increases the risk of complications. Following mergers, patients may not be aware that a formerly secular health care facility is now governed by Catholic directives.[15] Even if patients are aware of religious affiliations, survey data suggests that women nonetheless expect to receive medical services contrary to Catholic beliefs.[16]

Potential Remedies for Patients

Tort liability and immunity. Traditionally, the legal remedy for patients harmed by health care professionals has been to sue the clinician or organization for malpractice. Malpractice suits are based upon claims that the health care that plaintiff-patients received deviated from the standard of care and seek damages against individual clinicians or institutions for the harms caused by substandard care. Failure to provide care on the basis of conscience could expose clinicians to tort liability under the classical theory that compensation is required for legally cognizable harms caused by breaches of professional duties of care. As the third author has argued in more detail elsewhere, the content of professional advice is determined by the profession, and departures may result in liability for harm when the departure is based on justifications exogenous to professional knowledge.[17] Others have used informed consent doctrine to suggest that clinicians have a common law duty to disclose beliefs that constrict the scope of their practice as part of the duty of informed consent, which requires disclosure of the risks and benefits of a proposed course of treatment and any alternatives.[16]

Although there are colorable legal claims to hold religious or moral objectors, whether individual or institutional, liable for patient harms when they deviate from professional practice based on conscience, state law has largely

precluded these claims by immunizing objecting clinicians and entities. New Hampshire and Vermont are the only states without a health care conscience law.[18] A recent study of conscience law in the context of reproductive health care shows that 46 states have conscience laws protecting clinician or institution refusals to participate in abortions, of which 37 provide immunity from civil liability.[18] Some of these states even extend immunity to emergency situations when the life of the pregnant person is at risk.[18] Thirty of these states also protect clinicians and institutions from "disciplinary action."[18] Even when state statutes are silent as to immunity, judges deciding claims that stand or fall based upon compliance with a standard of care may interpret these conscience protection statutes as modifications of the standard of care that would negate any duty to patients to provide or refer out an "objectionable" service.[18] Consequently, patients who suffer harm as a result of a conscientious refusal to provide care would have tort remedies only in a small minority of states that do not have conscience protection statutes.

Remedies under the Emergency Medical Treatment and Active Labor Act (EMTALA). EMTALA is a federal law that provides important protections for all patients presenting with emergency conditions and active labor.[19] EMTALA requires hospitals that operate emergency rooms to screen individuals who present with these conditions and stabilize them before transfer or discharge. Thus, for example, a patient presenting with an ectopic pregnancy who is hemodynamically unstable should be stabilized by an emergency abortion and must not be turned away before this treatment is provided. However, if a patient is denied emergency care, EMTALA only allows patients to sue the hospital rather than the objecting clinician.[20] Moreover, the hospital may be unable to prevent future EMTALA violations, because it is prohibited from taking any adverse employment action against employees who object to certain emergency procedures.

It is important to note that a patient's claims against a hospital for harms incurred due to an EMTALA violation are limited to the personal injury law of that state. As described above, many states immunize the hospital from civil liability for harms resulting from a health care professional's conscientious refusal, leaving the harmed patient without recourse since EMTALA embeds states' civil liability standard into its mechanism for remedies. Moreover, EMTALA covers only a small subset of patients denied care because of a clinician or entity's deeply held beliefs. For example, a patient who was not advised on abortion options and subsequently failed to locate a willing entity prior to the viability deadline[13] will have been harmed by the objecting entity

but will have no remedy under EMTALA because the patient did not present with an emergency condition.

Antidiscrimination provisions. The Affordable Care Act (ACA) of 2010 includes an antidiscrimination provision that could be used if a patient is denied care "on the basis of sex." Section 1557 of the ACA provides that an individual shall not be subjected to discrimination in "any health program or activity, any part of which is receiving federal financial assistance."[21] Courts across the country have interpreted Section 1557 antidiscrimination protections as prohibiting denial of gender-affirming care because it is a form of sex discrimination. Although Section 1557 was enjoined from government enforcement in the Franciscan Alliance suit,[22] individuals have successfully used private rights of action to enforce their right to gender-affirming care under Section 1557.[23,24,25] These cases have hinged on the denial of coverage for procedures to treat gender dysphoria that are covered for other medical conditions (eg, mastectomies and breast reconstruction for individuals with mutations in BRCA genes). Decisions prohibiting discrimination in health care on the basis of sex can logically be extended to religious and moral refusals to provide gender-affirming care, although this line of argument has not yet been accepted by a court.

Transparency requirements. Given the serious limits on legal remedies for patients harmed by clinician and institutional refusals, perhaps the most important legal tool to protect patients would be to enable them to make more informed decisions about where they seek care. Disclosure requirements can serve this purpose. The data show that patients are unaware of limits on care posed by conscientious refusals.[16] Many clinicians whose conscience limits the scope of care they provide do not believe it is necessary to disclose their objections and the resulting limits on care to patients.[26] It is conceivable that the number of such clinicians will increase following enactment of more robust legal protections provided by state and federal statutes and regulations. Together, these conditions make disclosure critical to protect patients from harm before it occurs. These disclosure requirements, however, must be consistent with both First Amendment limits on compelled speech and religious freedom protections.

Some state conscience laws include disclosure and other patient-protective measures in their conscience regulation regimes; 5 states that protect conscience also impose a duty to notify the patient of the refusal.[27,28,29,30,31] Illinois not only has one of the broadest conscience protection laws but also places a duty on the facility to "adopt written access to care and information

protocols that are designed to ensure that conscience-based objections do not cause impairment of patients' health" and to ensure that patients are informed of their "condition, prognosis, legal treatment options … consistent with current standards of medical practice."[32]

Even in its new conscience-protective rule, HHS acknowledged the role of such disclosures to patients. The agency noted that "within limits, employers may require a protected employee to inform them [patients] of objections" to specific procedures, particularly if it is likely the clinician would be asked for a referral.[4] Additionally, the text of the rule provides that facilities "may also inform the public of the availability of alternate staff or methods to provide or further the objected-to conduct" with a notice in a reception area or other location where patients will have easy access to the information.[4] Currently, few states have strict disclosure requirements, and federal regulations leave disclosures up to institutional policy. Where religiously affiliated institutions dominate the caregiver space, transparency will likely be lacking.

Conclusion

The legal trend is toward increased protection for objecting clinicians and other entities, with few remedies for patients harmed by limitations in access to care. This trend tends to prioritize health care professionals' individual beliefs over their role as advisors. Short of a shift in the law, disclosure can help patients to make more informed choices when seeking care.

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AMA CODE SAYS

AMA *Code of Medical Ethics*' Opinions Related to Organizational Influence in Health Care

Abigail Scheper

Abstract

In recent decades, organized health care has displaced some traditional solo-practitioner physician roles. As larger organizations become more influential in the health care sector, American Medical Association (AMA) positions on professionalism and organizational development, as outlined in the *Code of Medical Ethics*, can help physicians navigate organizations' influence on practice.

Professionalism

Opinion 11.2.1 of the American Medical Association (AMA) *Code of Medical Ethics,* "Professionalism in Health Care Systems," offers guidance for health care organizations about "containing costs, promoting high-quality care for all patients, and sustaining physician professionalism." These goals are important in any health care organization, and, in order to protect patient-physician relationships, physicians are obligated to communicate transparently, mitigate possible financial conflicts, and recognize their primary obligations to patients.[1] Additionally, Opinion 3.1.5, "Professionalism in Relationships With Media," considers how physicians ought to conduct themselves when reporting on behalf of organizations that are involved in patient care.[2] Similarly, this opinion suggests the primacy of keeping patients' information private and upholding confidentiality, and it underscores the importance of deferring to organizational guidelines regarding releasing patient information.

Conflicts of interest are also discussed in the AMA *Code*. Opinion 1.2.3, "Consultation, Referral and Second Opinions"; Opinion 9.6.5, "Sale of Non-Health-Related Goods"; Opinion 9.6.9, "Physician Self-Referral"; and Opinion 11.2.3, "Contracts to Deliver Health Care Services," each describe conflicts of interest physicians face regarding referrals, employment contracts, and financial interests.[3,4,5,6] For scenarios involving potential conflicts of interest,

the AMA *Code* offers guidance in Opinion 11.2.2, "Conflicts of Interest in Patient Care."[7] The opinion states:

> The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Under no circumstances may physicians place their own financial interests above the welfare of their patients.
>
> Treatment or hospitalization that is willfully excessive or inadequate constitutes unethical practice. Physicians should not provide wasteful and unnecessary treatment that may cause needless expense solely for the physician's financial benefit or for the benefit of a hospital or other health care organization with which the physician is affiliated.
>
> Where the economic interests of the hospital, health care organization, or other entity are in conflict with patient welfare, patient welfare takes priority.[7]

This opinion underscores that, above all, the interests of a patient and beneficence must take precedence over a physician's or institution's financial gain.

Ethical Intervention

Opinion 10.7 of the AMA *Code*, "Ethics Committees in Health Care Institutions," addresses one way in which organizations can develop cultures that promote ethics in medicine—by advocating for organizational and practical oversight.

> In making decisions about health care, patients, families, and physicians and other health care professionals often face difficult, potentially life-changing situations. Such situations can raise ethically challenging questions about what would be the most appropriate or preferred course of action. Ethics committees, or similar institutional mechanisms, offer assistance in addressing ethical issues that arise in patient care and facilitate sound decision making that respects participants' values, concerns, and interests.[8]

Ethics committees can help health care organizations make policy and support practices that both serve patients and minimize harm.

The AMA *Code* urges individual physicians to promote ethical practice as well. Opinion 1.1.7, "Physician Exercise of Conscience," calls for organizations to preserve opportunities for physicians to act "in accordance with the dictates of conscience."[9] Nevertheless, physicians do not have unlimited freedom to act on their conscience.

> Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient.... In

general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer.[9]

In essence, regardless of what an organization may dictate, physicians are expected to act according to these ethical standards in order to ensure quality of care for every patient.

Physicians are also expected to promote public health and community access to care, regardless of their organizational affiliation. In Opinion 11.1.2, "Physician Stewardship of Health Care Resources," physicians are reminded to "be prudent stewards of the shared societal resources with which they are entrusted" as "[m]anaging health care resources responsibly for the benefit of all patients is compatible with physicians' primary obligation to serve the interests of individual patients."[10]

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POLICY FORUM

What Should Health Care Organizations Do to Reduce Billing Fraud and Abuse?

Katherine Drabiak, JD and Jay Wolfson, DrPH, JD

Abstract

Whether physicians are being trained or encouraged to commit fraud within corporatized organizational cultures through contractual incentives (or mandates) to optimize billing and process more patients is unknown. What is known is that upcoding and misrepresentation of clinical information (fraud) costs more than $100 billion annually and can result in unnecessary procedures and prescriptions. This article proposes fraud mitigation strategies that combine organizational cultural enhancements and deployment of transparent compliance and risk management systems that rely on front-end data analytics.

Fraud in Health Care

Growth in corporatization and profitization in medicine,[1] insurance company payment rules, and government regulation have fed natural proclivities, even among physicians, to optimize profits and reimbursements (Florida Department of Health, oral communication, September 2019).[2] According to the most recent *Health Care Fraud and Abuse Control Program Annual Report*, in one case a management company "pressured and incentivized" dentists to meet specific production goals through a system that disciplined "unproductive" dentists and awarded cash bonuses tied to the revenue from procedures—including many allegedly medically unnecessary services—they performed.[3] This has come at a price: escalating costs, fraud and abuse, medically unnecessary services, adverse effects on patient safety,[4] and physician burnout.[5]

Breaking the cycle of bad behaviors that are induced in part by financial incentives speaks to core ethical issues in the practice of medicine that can be addressed through a combination of organizational and cultural enhancements and more transparent practice-based compliance and risk

management systems that rely on front-end data analytics designed to identify, flag, and focus investigations on fraud and abuse at the practice site. Here, we discuss types of health care fraud and their impact on health care costs and patient safety, how this behavior is incentivized and justified within current and evolving medical practice settings, and a 2-pronged strategy for mitigating this behavior.

Costs of Fraud and Abuse

In 2016, the Centers for Medicare and Medicaid Services (CMS) spent $1.1 trillion on health coverage for 145 million Americans, $95 billion of which constituted improper payments connected to abuse or fraud.[6] The Federal Bureau of Investigation estimates that fraudulent billing—the most serious of program integrity issues—constitutes 3% to 10% of total health spending, contributing to inefficiency, high health care costs, and waste.[7] Fraudulent billing directly impacts both cost and quality as reflected in higher premiums, more expensive services, and patients' potential exposure to unnecessary and risky interventions, such as being prescribed a medication or undergoing surgery without medical necessity.[4,7,8] Public-private costs of fraud and preventive responses by the federal Health Care Fraud and Abuse Control Program are paid directly or indirectly by insurers, hospitals, and individuals through tax dollars and higher costs associated with both fraudulent payments and regulatory enforcement.

CMS categorizes fraud and program integrity issues into 4 categories: (1) mistakes resulting in administrative errors, such as incorrect billing; (2) inefficiencies causing waste, such as ordering excessive diagnostic tests; (3) bending and abuse of rules, such as upcoding claims; and (4) intentional, deceptive fraud, such as billing for services or tests that were not provided or that are undoubtedly medically unnecessary (and sometimes harmful to the patient).[9] Fraud reduction requires effective identification of these kinds of activities—or, as we prefer to call them, "behaviors"—and targeted deterrence strategies directed at their root causes, including systems issues. Some of these root causes are practice-site induced: optimizing volume, focusing on reimbursable and profitable services, and restructuring clinical staffing to include expanded use of medical assistants and clerical personnel to perform some patient care-related functions that might be construed as unlicensed practice. Increased corporatization and profitization of medicine can encourage behaviors that fall under the 4 categories.

Incentivized to Process More Patients?

Current reimbursement models incentivize physicians to engage in behaviors designed to "game the system" based on expectations for productivity that can compete with physicians' presumed obligations to provide patients with high-quality care. For example, corporate protocols or reimbursement restrictions can limit or at least affect physicians' prescribing of certain tests, procedures, or medications. Based on independent medical judgment, a physician might believe a diagnostic test or certain medication is medically necessary for a patient, only to find that the insurance company denies coverage or to be notified, for example, that a clinically preferred suture thread, skin graft, or preoperative prep solution will no longer be made available due to cost. Couple these externally imposed (reimbursement) protocols and internally mandated efficiencies with performance-based compensation models tied to relative value units (RVUs), and quality metric-guided physicians can find themselves pulled in 2 conflicting directions. In response, some physicians argue that overcoding and overbilling are not fraudulent but rather reflections of responsible, quality care.[10]

Compensation models can also incentivize gaming the system. In the 2016 American Medical Association (AMA) physician salary survey on compensation, on average, 52.5% of physician compensation came from salary, 31.8% from personal productivity, 9.0% from practice financial performance, 4.1% from bonuses, and 2.5% from other sources.[11] Only 19% of physicians were paid by a salary-only model.[11] However, the AMA noted that part of physicians' salary determination was tied to productivity in the previous year, leading the AMA to conclude that productivity's substantial role in physician compensation has been underestimated.[11] Thus, even salary is not incentive neutral, particularly when performance level is tied to potential employer sanction or the practical need to sustain the financial viability of the organization.

Wynia and colleagues report that physicians intentionally bend the rules and game the system for perceived patient benefit.[12] When payers deny claims for services, tests, or medications that physicians deem medically necessary,[13] some claim that upcoding should be distinguished ethically from fraud because the physician ostensibly acts in furtherance of the patient's best interest.[12,13,14] In a survey of 720 physicians, 39% reported that they manipulated reimbursement rules by exaggerating the severity of the patient's condition to avoid early discharge and/or changed the diagnosis or reported nonpresent symptoms to secure a needed treatment or service.[12] Unless these decisions can pass objective, peer scrutiny for medical necessity

and appropriateness of care, physicians among the 39% who manipulated reimbursement rules could be charged with criminal and civil Medicare fraud, face huge fines and imprisonment, and lose their licenses.

These incentives come at a cost to both physicians and patients. Berenson and Rich have shown that primary care physicians have long been frustrated by third-party claim submission deadlines and employment performance expectations.[5] Physicians report feeling rushed, prone to burnout, and professionally dissatisfied.[5] Importantly, physicians describe enforced patient contact-time limitations as counterproductive.[5] Such policies reduce or eliminate counseling and preventive services for patients who present with complex or chronic conditions and preclude offering long-term strategies for effective chronic disease management.[5] Cost-driven care strategies, disguised as efficiencies, may result in insufficient care and higher utilization of expensive acute and emergency services. CMS' 2019 final rule under the Medicare Physician Fee Schedule may reduce these cost-driven care strategies by increasing reimbursement for actual services rendered and by authorizing payment for remote patient monitoring, counseling, and check-ins, including when such care is provided by other health professionals.[15]

Fraudulent Integrity Measures?

The 4 categories of CMS program integrity violations can result from unintentionally false or mistaken documentation submitted for reimbursement or from negligent or intentionally false documentation. Billing errors and mistakes, misclassification of a diagnosis or procedure, or improper documentation can indicate lack of program integrity education.[16,17,18] Inaccurate coding or errors in documentation can result from improper or incomplete interaction with the patient's electronic health record (EHR) if the physician merely copies and pastes text, if the EHR self-populates from previous encounters, or if the algorithm prompts the physician to offer the patient potentially unnecessary or inappropriate services.[16,17] When do these types of behaviors become fraud?

Werner and colleagues indicate that time pressures, administrative burdens, and a sense of decreased autonomy to treat patients according to their best medical judgment drive physicians to game the reimbursement system.[13] To contain costs, payers may routinely deny initial claims, forcing physicians to submit appeals to insurers, knowing that most physicians (and the patients who wind up having to pay) lack sufficient resources to engage in the appeals process.[13]

Robin Hood Defense

Some physicians perceive themselves as operating in an unjust environment, as physicians must weigh the competing demands of compliance with reimbursement rules against their role as physicians to provide optimal patient care.[12] Recognizing physicians' ethical duty to uphold the principle of nonmaleficence stemming from the Hippocratic Oath and their legal duty to avoid malpractice liability, Tavaglione and Hurst assert that physicians have a duty to protect the patient against the system, even at the risk of their own potential self-interest.[14] Notably, physicians worried about prosecution for abuse or fraud may not object to reporting their own manipulation of reimbursement rules (in surveys) because these actions are driven by a perception of patient necessity. If so, more efforts by payers to control physician options might simply increase manipulation.[12]

Although most physicians oppose outright fraud, such as billing for services never rendered or subjecting patients to medically unnecessary tests, procedures, or medications, the marketplace is rife with behaviors that inflate health care system costs, produce inefficiencies, and harm patients. In the 2018 fiscal year, the Department of Justice won or negotiated $2.3 billion in judgments or settlements relating to health care fraud and abuse, including 1139 criminal fraud investigations.[3] Modifications to the Affordable Care Act were designed to enhance the Department of Justice's efforts to investigate and prosecute health care fraud by shifting from a "pay and chase" model to active fraud prevention using front-end data analysis, predictive analytics, and trend evaluation to screen providers and identify suspicious claims and aberrant billing patterns prior to payment.[19]

When Fraud Poses Risks to Patient Safety

In one of the largest settlements with an individual under the False Claims Act, Steven Wasserman was charged in 2013 with accepting illegal kickbacks and billing Medicare for medically unnecessary services.[20,21] In this case, another physician, the relator (whistleblower) provided evidence that Wasserman was financially motivated to perform (and was reimbursed for performing), among other things, unnecessary surgeries—biopsies and tissue excisions on elderly patients. Wasserman settled the case by paying $26.1 million to resolve the allegations without admission of liability.[20,21] Such allegedly fraudulent practices not only created unnecessary expense but also, most importantly, exposed vulnerable adults to the risk and discomfort of unneeded procedures.

Another case, which involved both false claims and criminal claims against individuals affiliated with a pain management clinic, further illustrates the direct impact of fraud on patient safety and quality of care. In this case from 2018, an unnamed physician and the owner of a pain management clinic were both sentenced to 35 years in prison following a jury determination of criminal liability related to the illegal distribution of controlled substances.[3] A pain management clinic operated as a "pill mill" by distributing controlled substances at a profit in excess of $30 000 per day, with the physician seeing as many as 60 patients per day and writing over 18 000 prescriptions for hydrocodone over approximately 2 years.[3] These cases illustrate the more serious program integrity issues in which physician behavior does not arise from inadvertent mistakes or bending the rules to fulfill a duty to the patient but rather from intentional and fraudulent deception designed to increase profit at the expense of patient well-being.

Solutions to Mitigate Fraud and Abuse

We propose a multi-layered strategy to address program integrity issues that emphasizes education and employers' implementation of front-end analytics to mitigate fraud and abuse at the practice site. Here, we highlight elements of this strategy that are natural expansions of existing quality control and fraud prevention systems and objectives.

Program integrity education. Program integrity and fraud control must start in undergraduate medical education and remain an explicit component of residency mentoring, which is the job of medical school deans, department chairs, and division directors and preceptors. The already traffic-jammed curriculum could be gently massaged—to weave in a bit more about patient safety, malpractice, quality assurance, evidence-based medicine, and appropriate billing practices. A special program could also be implemented during medical school or employment to address program integrity issues arising from mistakes and inadvertent errors in both EHR charting and billing. The literature suggests that comprehensive education in this area is lacking, with only about one-third of medical schools providing any curricular content relating to fraud and abuse.[17] In response, some stakeholders recommend resident physician education that would cover issues pertaining to compliance, billing, appropriate documentation, adequate supervision, and potential civil and criminal liability.[16,17,18] A variety of training models exist, and several commentators suggest integrating program integrity training as part of the physician onboarding process.[16]

Front-end analytics. In the past decade, addressing egregious fraud has moved away from the pay-and-chase model to using data analytics and big data to assess the legitimacy of claims prior to payment.[3,6] CMS currently utilizes the Fraud Prevention System, which applies algorithms to monitor and analyze incoming claims and payments. Flags are automatically placed on outliers, which the Office of the Inspector General of the US Department of Health and Human Services can further investigate, along with provider risk ratings and peer comparisons.[3] Using real-time data collection, the Office of the Inspector General can compare patient volume for similar professional claims to identify abnormally high reimbursement submissions, unnatural practice growth patterns, or unusually high numbers of procedures based on specialty and practice size or to flag suspect patient visits patterns (such as an excessive number of patients during a 24-hour window.)[22,23] This artificial intelligence-based system for identifying potential program integrity anomalies is relatively new. But CMS is also directed to cases by whistleblowers, who are incentivized to report fraud under the False Claims Act and Stark Law (ie, prohibition on self-referral), which entitle them to receive a percentage of any government recoveries.[24,25]

In addition to traditional mitigation strategies such as hiring qualified quality assurance and compliance personnel and utilizing CMS provider resources that offer ongoing education, we recommend as part of risk management that providers internally implement predictive analytics programs such as those offered by technology consulting entities[26] to identify patterns of aberrant and suspicious billing practices prior to submission of claims. Adopting a program that predicts, classifies, and flags potential events prior to claims submission would empower institutions and physician groups to reduce unintentional error, avoid costly liability, and prioritize patient safety. It is not unreasonable to expect that regulators might one day place the onus on practices and facilities to internally screen claims submissions using "certified" predictive analytics software driven by algorithms that might even be able to detect the Robin Hood physician with the best patient care intentions. Those who use fraud mitigation software might be rewarded with differential payment rates; those who don't might be taxed. But treating fraud and abuse must really start at home—in medical education, residency, and practice—where physicians are expected to "heal thyself" first.

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MEDICINE AND SOCIETY

Do Conflict of Interest Disclosures Facilitate Public Trust?

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Abstract

Lab experiments disagree on the efficacy of disclosure as a remedy to conflicts of interest (COIs). Some experiments suggest that disclosure has perverse effects, although others suggest these are mitigated by real-world factors (eg, feedback, sanctions, norms). This article argues that experiments reporting positive effects of disclosure often lack external validity: disclosure works best in lab experiments that make it unrealistically clear that the one disclosing is intentionally lying. We argue that even disclosed COIs remain dangerous in settings such as medicine where bias is often unintentional rather than the result of intentional corruption, and we conclude that disclosure might not be the panacea many seem to take it to be.

Introduction

While most medical professionals have the best intentions, conflicts of interest (COIs) can unintentionally bias their advice.[1] For example, physicians might have consulting relationships with a company whose product they might prescribe. Physicians are increasingly required to limit COIs and disclose any that exist. When regulators decide whether to let a COI stand, the question becomes: How well does disclosure work? This paper reviews laboratory experiments that have had mixed results on the effects of disclosing COIs on bias and suggests that studies purporting to provide evidence of the efficacy of disclosure often lack external validity. We conclude that disclosure works more poorly than regulators hope; thus, COIs are more problematic than expected.

Perverse Effects of Disclosure

Several studies have reported positive effects of disclosure. Koch and Schmidt's recent lab experiments suggest that disclosure reduces bias in advice when audiences receive feedback and advisors can form reputations.[2]

Similarly, Church and Kuang argue that disclosure mitigates bias when the audience can sanction advisors for giving bad advice.[3] Furthermore, Sah argues that disclosure reduces bias in clinical settings because practitioners operate under the ethical norm of "clients first."[4] The problem, as we shall explain, is that these experiments rely on disclosures that make it unrealistically clear that advisors are intentionally lying to advisees.

The experiments were a response to earlier studies conducted by Cain, Loewenstein, and Moore (CLM)[5,6] that suggest disclosure might have perverse effects. For example, CLM argued that disclosure can increase bias in advice due to 2 possible psychological mechanisms. *Moral licensing* to bias advice suggests that, postdisclosure, advisors (perhaps unintentionally) show less self-restraint because "the patient has been warned."[5] Prior to disclosure, conflicted advisors rein in their bias; they want to help themselves, but they also (or even primarily) want to help their advisees. Postdisclosure, they might feel less obliged to help their advisees if they think that the advisees can help themselves, having been warned. Second, postdisclosure, advisors might use *strategic exaggeration* to further bias their advice in order to counteract presumed advice-discounting from advisees. It's as if disclosure causes advisees to cover their ears—and also encourages advisors to yell even louder.

Sah, Loewenstein, and Cain[7,8] demonstrated further perverse effects, including the *burden of disclosure*,[7] whereby disclosure causes advisees to feel burdened to follow biased advice. After disclosure, advisees are concerned about the advice being untrustworthy, but they also want to avoid *being seen* as noncompliant[7] or distrusting of the advisor.[8] This compliance diminishes if advisees can quietly "exit" the prying eyes of advisors, hide their noncompliance, or somehow make another excuse for noncompliance other than distrust.[9] A more basic perverse effect is that overreliance on disclosure might supplant efforts to reduce COIs; although this idea is less psychologically complex, it is perhaps the most consequential.

In addition to perverse (backfire) effects, disclosure might simply fall short. For example, regulators often call for more frequent, easier-to-understand disclosures. Although disclosures buried in fine-print legalese help only those doing the burying, research on anchoring and insufficient adjustment[10] suggests that *even when audiences are clearly warned* that the advice was randomly generated, they are still affected by the advice. Thus, disclosures might not totally undo the damage of biased advice, regardless of how clear the disclosures are.

Prodisclosure Research and Its Limitation

Despite these findings on the weaknesses of disclosure, other studies (Koch and Schmidt,[2] Church and Kuang,[3] and Sah[4]) have sought to defend disclosure. However, in these experiments, what is disclosed is clearly identifiable, intentional lying. Lying is often not present in medical contexts—or, at least, not easily identified. For example, consider physicians who had business relationships with makers of opioids during the overprescription crisis (eg, through taking consulting gigs, abundant "free samples," or even traditional rewards for treating patients). Even in cases of overprescription, it is likely that many conflicted physicians reasonably—or, at least *plausibly*—believed the drugs were appropriate to alleviate pain. After all, even many of those who advised that Enron was a "strong buy" plausibly believed their recommendations.[11] Our point is that if mere disclosure made it easy to prove who was intentionally giving self-interested advice, prodisclosure arguments would unsurprisingly win out. Unfortunately, it is not so easy to identify intentionally biased advice in real-world contexts. And in real-world contexts, COIs often lead to unintentional bias rather than intentional lies.[12]

Granted, even CLM's own experiments sometimes examined intentionally biased advice. For example, in one study, CLM had advisors rate the ethicality of intentionally providing advice outside a range containing the actual number (of jelly beans in a jar).[5] However, in the *main* CLM experiments, advisors were asked to give advice that was within a broad range of plausible values[5] or else no range was given.[6] Whether or not advisors' bias was intentional, it was realistically difficult for advisees to know if advisors believed the advice. In other words, CLM's advisors had *plausible deniability*. Research has shown plausible deniability to be crucial to advisors, even in one-shot experiments.[13] It is easy to imagine why plausible deniability would be important in the real world—not only to intentional liars who seek protection from litigation, but also to the unintentionally biased who could not otherwise escape (perhaps their own) scrutiny.

Similar to CLM,[5,6] Koch and Schmidt[2] tested how advisors' disclosure of COIs affected the advice they gave when they knew the range of true values. In both CLM's and Koch and Schmidt's studies, advisors gave numerical advice to advisees playing numerical guessing games (eg, guessing a random value, estimating the value of coin jars, estimating sale prices of local houses). The advisors had COIs because they were paid more when advisees overestimated the value of the item in question. Koch and Schmidt provided very narrow ranges of the true value to the advisors, and many of their

advisors gave (knowingly false) advice that was outside this range.[2] Conversely, CLM gave advisors less information about the true value (broader ranges), so CLM's advisors could plausibly deny giving bad advice if it remained within the given range of values. The studies incorporated feedback of advisors' and advisees' estimated values that could be taken into account in the next round of advising; however, in Koch and Schmidt's study, advisee feedback often made it unrealistically clear that the advisor was lying because their estimates were outside the range of true values. As a result, disclosure that the advisor had a COI would be especially damning when coupled with the now obvious fact that the advisor had lied in the prior round. It is not realistic for advisees to receive such detailed external feedback or for advisors to even know the range of true values. The advisors in CLM's studies disclosed COIs but often could have plausibly given well-intentioned advice because the range of true values was so broad. The difference is one of being warned that *your physician intentionally lies to you* vs being warned that *your physician might be biased*.

Similar problems abound in Church and Kuang's study on combining disclosure with sanctions.[3] Advisors knew that advice outside a certain range would be unequivocally wrong, but the findings suggest that many advisors still gave intentionally wrong advice (ie, outside the true range) when COIs were not disclosed. Disclosure would highlight the possibility that advisors were lying or biased, so it is not surprising that advisors would lie less when liars could easily be punished: advisees merely needed to select sanctioning options, and liars were automatically punished by the experimental system, regardless of whether advisees were aware that the advisor was lying. Church and Kuang admit to this limitation, stating, "In our setting, an adviser who provided bad advice would be penalized with certainty, as long as the investor chose to initiate sanctions."[3] They credit an anonymous reviewer for pointing out the problem here: "in many naturally occurring settings, when advice turns out to be bad, it might be difficult to discern whether that is due to the adviser's bias or uncontrollable factors such as environmental volatility. As a result, biased advisers [Cain and Banker would add: 'in the real-world'] are not necessarily penalized.... We acknowledge that under such circumstances, the investor's threat of initiating sanctions might have less teeth than in our setting." At least Church and Kuang acknowledge this limitation: disclosure reduces bias when sanctions have (unrealistically) sharp teeth and bad advisors can be identified.

Sah argues that disclosure reduces advisee bias when, as in medicine, there are strong ethical norms to "place patients first."[4] Yet in some of Sah's

experimental designs in medical or financial contexts, medical advisors are warned that option A is clearly more beneficial to the audience than the advised option B, so the given medical advice (B) has no plausible deniability; but the financial advisors (who are in a role similar to advisors in CLM's experiments) have plausible deniability. The reader is left wondering: Is it the medical context or the lack of deniability that reduces bias? When Sah's designs correct this confound (by removing plausible deniability in both medical and business settings), the evidence merely suggests that disclosure reduces *intentional lying* when medical norms are manipulated. This is not evidence that disclosure reduces mere *bias* in medical settings. Since many medical contexts include problems of bias that go beyond intentional lying, the above flaws highlight the lack of external validity of Sah's prodisclosure experiments.

Real-World Problem of Conflicts of Interest

Most physicians (even biased ones) are not awake at night, thinking how to get rich by intentionally harming patients. Unfortunately, lay people's views of COIs (and even the view sometimes implied by prodisclosure research) often trade on a misconception that failure to properly navigate a COI is a problem of intentional corruption (ie, bad apples). This erroneous model depicts physicians as thinking, *I know that option A is best for my patients, but option B is best for my wallet. What should I do … B?* This scenario gets the psychology wrong. COIs are not dangerous just for the intentionally corrupt Bernie Madoffs of the world. COIs are dangerous for people prone to unintentional bias—basically everyone.[14,15]

The last 30 years of social science research has taught us that the human mind is simply not good at being objective.[16,17] When physicians disclose a COI, it is not enough to trust that they *want* to be objective if they are psychologically incapable of being objective. Reducing bias is easier in black and white cases in which the physician knows for certain what is the best course for their patients. However, objectivity is more difficult in realistic gray areas in which the best course is uncertain. It's there that advisors might plausibly think that they can have their objective cake and eat it, too, thinking, *I know that option B is best for my wallet, but, of course, I put my patients first. The question is: What is best for my* patients*? That is less clear. It could also be … B*.

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MEDICINE AND SOCIETY

How Should We Judge Whether and When Mission Statements Are Ethically Deployed?

Kellie E. Schueler and Debra B. Stulberg, MD

Abstract

Mission statements communicate health care organizations' fundamental purposes and can help potential patients choose where to seek care and employees where to seek employment. They offer limited benefit, however, when patients do not have meaningful choices about where to seek care, and they can be misused. Ethical implementation of mission statements requires health care organizations to be truthful and transparent about how their mission influences patient care, to create environments that help clinicians execute their professional obligations to patients, and to amplify their obligations to communities.

Ethics, Mission, Standard of Care

Mission statements have long been used to communicate an organization's values, priorities, and goals;[1] serve as a moral compass for an organization; guide institutional decision making; and align efforts of employees.[2] They can also be seen as advertising to prospective patients and employees. Although health care organizations' mission statements serve these beneficial purposes, ethical questions (especially about business practices seen as motivating profit by rewarding underutilization[2,3,4]) arise when mission implementation conflicts with acting in the best interests of patients. Ethical questions also arise when religiously affiliated organizations deny clinically indicated care in order to uphold their religiously based mission. For example, a Catholic organization's mission statement might include phrases such as "faithful," "honoring our sponsor's spirit," or "promoting reverence for life" and likely accords the Ethical and Religious Directives for Catholic Health Care Services, which Catholic organizations' clinicians are required to follow as a condition of employment or privileges.[5]

When strictly followed, these directives restrict health care service delivery, such that patients—particularly those seeking contraception, pregnancy termination, miscarriage management, end-of-life care, or other services perceived as conflicting with Catholic teaching—are not given the standard of care. Federal and state laws protect conscience rights of organizations, allowing them to refuse to provide services that conflict with the deeply held beliefs and values that drive their mission.[6] Recognizing the potential for conflict between mission statements and patients' autonomy or best interests, we maintain that health care organizations have fundamental ethical and professional obligations to patients that should not be superseded by a mission statement.

Using mission statements of religiously affiliated hospitals as a useful test case, we perform an evidence-based analysis to address the question of what ethical obligations health care organizations have to patients and to determine which criteria should be used to judge whether a mission statement is deployed in an ethical manner. We argue that an organization must be honest and transparent about its mission and the ways it might affect patients; must allow all physicians who wish to act on their conscience to provide safe, high-quality care that fulfills professional standards; and may deny care only when it is actually feasible for patients to access reasonable alternative care.

Transparency

Given that mission statements serve as tools to communicate with prospective patients, it is essential that these statements truthfully and clearly portray the priorities of the health care organization. Furthermore, in implementing its mission, a health care organization should be transparent about the ways in which its mission might alter or restrict patient care. Studies of reproductive care restrictions at Catholic hospitals have demonstrated the importance of this type of transparency. A recent survey demonstrated that most women desire information about restrictions on care at religious institutions in order to decide where to seek reproductive care.[7] In practice, however, women often lack the information needed to make informed decisions regarding whether to seek reproductive care at a religiously affiliated hospital because some hospitals lack transparency about their religious affiliation or its implications for patient care. A recent study found that though 79% of Catholic hospitals report their Catholic affiliation on their website, only 28% describe how this affiliation affects the care they can provide patients.[8] The need for improved transparency was demonstrated by a recent national survey's finding that 37% of women whose primary hospital

was Catholic were unaware of its religious affiliation.[9] In addition, many women do not anticipate the restrictions that can be in place at religious hospitals. When surveyed about their expectations for reproductive care at a Catholic hospital, 69% of women expected that they could receive birth control from an obstetrician/gynecologist (OBGYN), 63% that sterilization would be available, 44% that in vitro fertilization would be available, and 27% that abortion would be an option if the fetus had a serious health condition.[10] The directives that doctors in Catholic facilities must follow prohibit provision of all of these services, but many women did not anticipate denials of care.

Chervenak and McCullough, who have written extensively about ethics in obstetrics, argue that lack of transparency in hospitals' reproductive health policies places the principle of respect for patient autonomy "at risk of systematic … compromise."[11] The recent trend in hospital mergers and acquisitions adds confusion, as policies can change rapidly.[12,13] Formerly secular institutions purchased by religious health care systems may retain their secular name and mission statement while following the Catholic Directives.[14] Based on values of truth telling and respect for patient autonomy, health care organizations have a duty to inform potential and current patients about ways in which their missions might limit or change the services they provide.

Conscience

When physicians are faced with a conflict of interest—between organizational priorities and patient well-being, for example—commonly accepted ethical standards dictate that physicians give primacy to the needs of their patients.[15] Physicians can be caught in these conflicts because of their dual identities as clinicians and representatives of their institution.[16] In a 2011 nationally representative survey of practicing obstetrician-gynecologists (OB-GYNs), 37% of those who worked in religiously affiliated hospitals reported conflicts with their institution over religious policies for patient care; that number rose to 52% among OB-GYNs who worked at a Catholic institution.[17] These physicians reported instances in which their hospitals, on moral grounds, prevented them from providing what they considered to be the standard of care for obstetric complications and emergencies.[18,19] Harm in various forms—from inconvenience to serious morbidity and mortality—can befall patients when physicians are not allowed to practice according to the professional and ethical standards of medicine.

Although obligated to act in the best interest of their patients, physicians, like institutions, have a legal right to refuse to provide care that conflicts with

their conscience.[20,21] While the federal government recently strengthened legal protections for clinicians who *refrain from* providing a service based on conscience,[22] the right *to provide* a service according to one's conscience has been less vigorously defended. For instance, when physicians are compelled by conscience to provide abortion, some hospitals have prohibited them from doing so even in their free time.[23] In this way, our current legal system values the conscience of those refusing to provide care above the conscience of those willing to provide care to a willing patient.[24] A developing legal case in Colorado, in which a physician was fired by a religiously affiliated institution over the provision of aid-in-dying medication, will test the legality of valuing the conscience of a corporation over the conscience of a physician who feels compelled to provide care.[25]

It is in this legal setting that health care organizations must navigate the ethical implementation of their mission statements. When operationalizing the moral tenets of a mission statement, an organization is ethically obligated to prevent patient harm by creating an environment in which the conscience of individual clinicians is respected and in which they are able to faithfully fulfill the professional and ethical standards they have sworn an oath to uphold.

Referrals

In cases in which an organizational mission prevents a patient from receiving needed care, referral to a willing institution is often pointed to as a solution. However, whether clinicians and institutions are morally obligated to make referrals for services they refuse to provide is debated. The American Medical Association (AMA) *Code of Medical Ethics* makes it clear that referral should be the default action when a clinician or institution refuses to deliver needed care but doesn't outright require referral.[26] The American College of Obstetricians and Gynecologists Committee on Ethics makes a stronger appeal, arguing that clinicians who refuse care have a "duty to refer patients."[27] A national survey of physicians demonstrated that the majority (71%) believe they have a moral obligation to refer in such circumstances.[28]

In reality, referral is only a morally acceptable option if patients have access to reasonable alternatives for care. The growth of Catholic health systems has made it increasingly difficult for patients to find institutions that don't restrict the options available for reproductive or end-of-life care, as 1 of 6 acute care hospital beds in the United States is at a Catholic institution.[13,29,30] This lack of access is amplified by geography and financial insecurity. For instance, research in Cook County, Illinois, found that most women receiving public

insurance are enrolled in plans that have an overrepresentation of Catholic hospitals.[31] In addition, the federal government has designated many Catholic hospitals "sole community hospitals" in recognition that alternative secular facilities are often prohibitively far away for patients.[12] Physicians have noted financial barriers as a leading reason why referrals for services prohibited in Catholic hospitals were inadequate to meet patients' needs.[32]

The AMA *Code* recognizes lack of access as an important consideration in physicians' exercise of conscientious objection, noting that physicians have "stronger obligations" to act against their conscience and in the best interest of the patient when a patient cannot reasonably receive the care from another physician or institution.[26] Ethicist George Annas calls the transfer of patients to willing facilities "ethical dumping," arguing that it should not be considered a morally superior option because it inflicts harm on patients.[33] Ultimately, referrals are only an ethical alternative to providing the requested service if patients are able to act on the referral without facing significant burdens in travel, cost, or time. Given the barriers to accessing reproductive health care discussed above, in many areas of the country and for many patients with limited resources, these burdens are prohibitive.

Conclusion

Fundamental ethical principles of medical care are not altered by organizations codifying and communicating their priorities in the form of mission statements. Thus, in deciding whether an organization has ethically formulated and implemented its mission statement, we recommend asking the following questions: First, is the organization truthful and transparent about its mission and the ways it might affect patient care? Second, does it create an environment that respects and supports the ethical and professional obligations of its physicians, allowing them to put the needs of the patient first? If these 2 questions are answered in the affirmative, then the mission statement is ethical. In addition, relying on referrals or transfers-of-care for needed services that conflict with an organization's mission is only ethically acceptable if patients truly have access to reasonable alternatives for their care. Health care organizations have obligations to patients that cannot be superseded by ideas laid out in their mission statements. Indeed, they must avoid causing harm to patients that compromises the ethical underpinnings of the medical field and instead must support clinicians in their dedication to serving patients.

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HISTORY OF MEDICINE

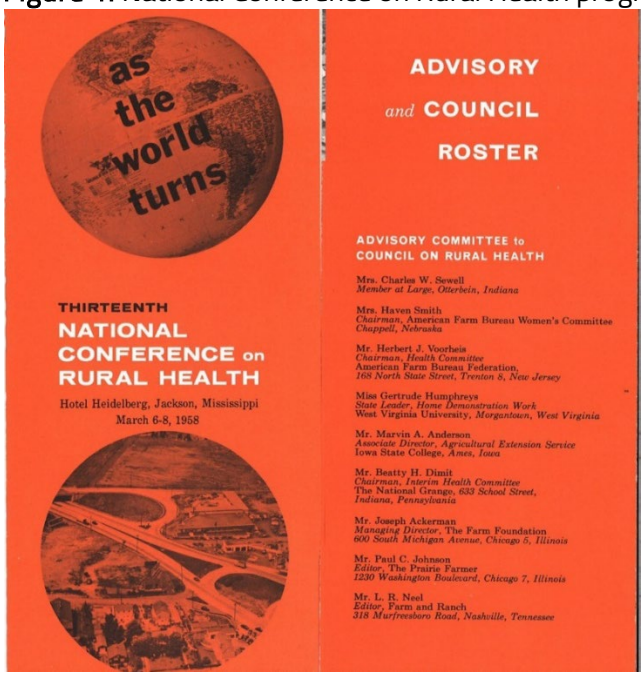
Community Health in Rural America During the Mid-20th Century

Amber Dushman, MA, MLIS

Abstract

The Council on Rural Health (1945-1975) of the American Medical Association (AMA) collaborated with domestic health care organizations in the mid-20th century to improve access to health care in rural areas. This council promoted health and farm safety education, public health measures, insurance plans, and construction of health facilities. It also lobbied state and county medical societies to form rural health committees. AMA archive materials document these activities and demonstrate physicians' involvement and investment in the communities they served.

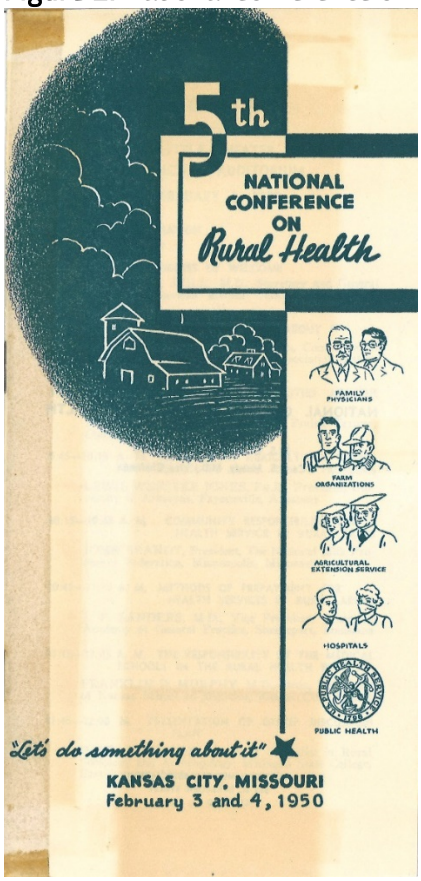
Figure 1. National Conference on Rural Health program, 1958



Courtesy of the American Medical Association Archives.[1]

The Conference on Rural Health was the culmination of hard work by farm women, led by Edna Sewell of Otterbein, Indiana. Sewell, director of the Associated Women of the American Farm Bureau Federation, recognized the need for better health care in rural areas and engaged the medical profession. Because of her efforts, the American Medical Association (AMA) set up the Council on Rural Health (CRH) in 1945 to address rural health needs through annual conferences and community health councils. The council also helped connect rural physicians throughout the country. Although the CRH was disbanded in 1975, it helped to prepare rural health care for dramatic changes to health care in the United States over the next 30 years.

Figure 2. National Conference on Rural Health program, 1950



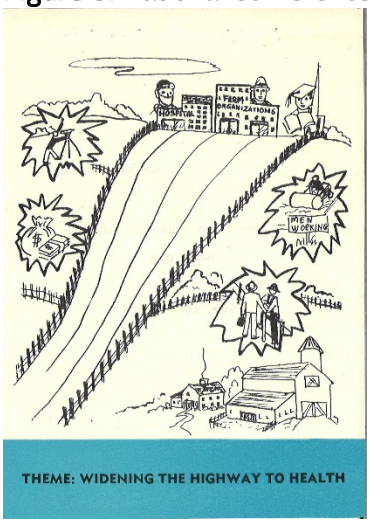
Courtesy of the American Medical Association Archives.[2]

Supported by the National Grange of the Order of Patrons of Husbandry, or "the Grange" for short, the CRH originated in 1945 as the Committee on Rural Medical Service and became an AMA council in 1951. The Grange is a community organization in the United States with roots in agriculture. Founded in 1867, the Grange promotes the economic and political well-being

of the agricultural community. From its inception, the Grange advocated for farmers' causes such as rural access, rural postal delivery, and bringing electricity to the rural areas of the United States. The CRH complemented the Grange's goals by actively promoting health and farm safety education and sponsoring annual rural health conferences, public health measures in rural areas, insurance plans, and construction of health facilities. The CRH also lobbied state and county medical societies to form rural health committees.

By the sixth meeting of the council, in 1950, the CRH felt it was nearing solutions put forth by rural communities. Whereas the farming communities viewed getting a physician into the village as the biggest hurdle to health care, the AMA viewed the personnel shortage as only one of several issues. The AMA emphasized the difference between health and medical care and focused on personal and community responsibilities for health, including proper diet, sanitation, safe surroundings, and immunizations against preventable disease. Without citizens' knowledge of these responsibilities for health, physicians and nurses would be less effective. The CRH reported that "the physician is helpless unless the public is educated to these facts."[3] The CRH advised that local health councils are good channels for teaching health to rural citizens.

Figure 3. National Conference on Rural Health program, 1953



Courtesy of the American Medical Association Archives.[4]

Conference conversations centered on community health councils as a way to channel medical guidance to the rural public. Local rural councils included civic, agricultural, professional, municipal, and religious-based public health efforts.

Veterans groups, women's groups, the Red Cross, and others also promoted communities' engagement in rural health.

Figure 4. National Rural Safety program, 1963

Courtesy of the American Medical Archives.[5]

The CRH, in cooperation with the National Safety Council, national farm organizations, and allied health groups, sponsored a National Rural Health Safety Conference held in Chicago, Illinois, April 5-6, 1963. The theme of the conference was community-based approaches to farm and home safety. A major goal of the conference was to help improve communication between individuals and groups interested in rural health and safety problems. During the conference, national organizations made reports available about resources that could be disseminated by state and community groups. Farm equipment manufacturers also attended to promote their newest safety devices and offer demonstrations pertaining to health and safety. Of note was a panel session, "Rural Safety as Seen by: A Practicing Physician, a Psychologist, a Psychiatrist, and an Orthopedic Surgeon."

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ART OF MEDICINE

Justice Is the Best Medicine. And, Yes, You Can Call Us by Our Pronouns

Ryan Brewster

Abstract
One recent essay suggests that emphasis on social justice in medical education is done at the expense of clinicians' technical competency. This response to that stance is a digitally illustrated series that contextualizes patient health as both physiological and determined by social, economic, and cultural conditions.

Figure. Detail from *Justice Is the Best Medicine. And, Yes, You Can Call Us by Our Pronouns*

(Click here to view the entire illustrated series.)

Media

The illustrations were rendered digitally in Adobe Photoshop and Procreate.

Caption

A recently published opinion in the *Wall Street Journal*[1] claims that recent emphasis on social justice in health professions education has come at the expense of developing clinicians' technical competencies. This digitally illustrated series is based on my experiences as a medical student and seeks to convey that justice is inseparable from good health policy and solid health care practice. The series represents how patients' health and well-being is contextualized in light of physiological, social, economic, and cultural conditions. These visuals and accompanying text offer a perspective in the ongoing conversation among clinicians, educators, and trainees to define the next generation of health care.

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PERSONAL NARRATIVE

Pronouns and Advocacy in Medicine

Nat Mulkey, BUSM

Abstract

In September 2019, a prominent dictionary recognized *they* as a proper pronoun for nonbinary individuals. This change can be seen as a source of newfound legitimacy for students and trainees self-advocating for nonbinary pronoun recognition in health care practice and training. This article considers one student's experience after coming out as nonbinary and voicing that their pronouns are they/them.

Singular *They*

On September 17, 2019, the *Merriam-Webster Dictionary* added a definition to the word *they*, stating that it can now be used as a singular pronoun for an individual who is nonbinary.[1] The use of *they* to refer to a single person has been linguistically common prior to this addition.[2,3] I personally had already been using they/them pronouns for months before this announcement, but the addition of a new definition of *they* to the dictionary was still affirming. As a third-year medical student in a revolving door of clerkships—involving another revolving door of residents and attending physicians—my pronoun use comes up almost daily. "Hi, my name is … and my pronouns are they/them." This introduction might seem simple, but it took workshopping. I dropped, "I *prefer* they/them pronouns," because relegating them to just a preference seemed to convey to my audience that there were other pronoun options that were acceptable to me, which is untrue. I also tried, "I *use* they/them pronouns." This particular format also created an "out," suggesting that /use these terms, but not everyone does or has to. I am happy with what I have settled on. Now with this dictionary update, when I introduce myself, I am doing so with society's approval, whereas before, it was only by my own desire. And indulging one's own desires in medicine often feels wrong.

Self-sidelining and Bad Reasoning

Before third-year clerkships kicked off, a dean of student affairs gave our class a reality check. No more sweatpants, no more rolling into lecture 15 minutes late, no more complaints about lecture-slide quality. This process is

no longer about *us* and we are not the focus—the patients are. Speeches like this one can be important for students embarking on the journey of becoming a health care professional. All of our actions should be fueled by what is best for the patient. Unfortunately, this widespread mindset can become extreme.

Many health care professionals sideline their own needs and desires, a practice some construe as a basic ethical value, like respect for the autonomy of patients, beneficence, nonmaleficence, and justice.[4] Sidelining one's own needs can be helpful when it is important to focus concretely on patients' vulnerabilities and not on one's own. Staying late, working through lunch, squeezing in a patient who is 2 hours late, examining and processing patients' electronic health record (EHR) when at home, and monitoring patients during time off are examples of self-sidelining that are common in the lives of physicians.[5] There are good reasons to be wary of extremist self-sidelining. When our mental well-being is compromised by extreme self-sidelining, our patients might suffer with us, or even because of us. There are consequences of this kind of extremism that I am not willing to bear.

That said, my need to be identified correctly and to avoid being misgendered every single day should not be pitted against the needs of my patients. The vast majority of my time is spent with resident physicians who are spread so thin you can see through them. At first, taking even an extra second to include my pronouns in my introduction seemed wrong to me. I felt guilty taking up residents' time with my lengthy, perhaps complicated, introduction. This guilt led me into fallacious thinking that residents' time spent navigating my pronouns meant less time spent on patients. And then there were the patients themselves. Actually, I have not even attempted an introduction with my pronouns to a patient. Why would I? I've been trained to think that honoring my own truth is indulgent and self-focused rather than patient focused. But there's the fallacy again: the false choice that I must either respond to my vulnerabilities or respond to theirs. Better reasoning about whose interests are at stake in clinical encounters comes from rejecting this false dilemma and acknowledging that clinical encounters are things we need to do together.

Experiences of Transgender and Gender Nonbinary Trainees and Patients

It is well established that lesbian, gay, bisexual, transgender, queer plus (LGBTQ+) individuals face substantial health disparities compared to the general population.[6,7,8] To address these disparities and improve patient care, the medical community has started to integrate more training on LGBTQ+ health into medical education.[9] Resources specifically targeting pronoun use

among clinicians are also available.[10] There have even been calls to make EHRs more inclusive of nonbinary patients and proposals for an embedded pop-up in EHRs when a patient self-identifies as nonbinary.[11] Much work still needs to be done, but it is safe to say that patient-centered advocacy is underway regarding LGBTQ+ individuals, including those who are transgender and gender nonbinary (TGNB).

A recent study examined experiences of TGNB medical students and physicians.[12] The researchers found that 22% of participants reported barriers attributable to their gender identity while applying to medical school and 43% while applying for residency. They also found that 78% of participants censored themselves during training to avoid disclosing their TGNB identity and that 69% heard derogatory comments about TGNB individuals during their training or practice. Although this study was based on a small sample, it is among the first to investigate experiences of TGNB medical trainees during processes of medical socialization. It is telling because it illuminates ways in which phobic attitudes and blatant discrimination might undermine TGNB individuals (or anyone else who struggles with prejudice and discrimination) who are patients.

So far, TGNB (and more generally LGBTQ+) advocacy efforts have targeted patients' experiences. Efforts to be more inclusive and provide better care for TGNB patients are extremely important, and all clinicians should convey the same degree of inclusivity and collegiality with TGNB trainees. Why would we expect to be able to provide high-quality, inclusive care to patients if we cannot live out the value of inclusivity among our colleagues? A thorough analysis to inform TGNB-friendly practices at an institution cannot be done without thoughtful reflection and introspection on that institution's own training environment for TGNB trainees.

Embracing Them

In a past clerkship orientation, I and other students went around the room for introductions. We were supposed to state our name, clerkship location, and interests. It began as I expected: no one stated their pronouns. So, I gathered my courage and prepared to add *they/them* to my introduction. But before my turn, a good friend of mine confidently concluded her introduction with "my pronouns are she/her." I followed her with uninhibited gratitude. It might, and does, seem silly to many people to include their pronouns in their introductions. But it is an ethically important step toward normalization of inclusive pronoun use and nonbinary identities. There is not much data on the prevalence of nonbinary individuals. One study, based on the 2016 Minnesota

Student Survey, found that 2.7% of adolescents in the sampled population identified as gender nonconforming.[13] And the 2015 US Transgender Survey showed that more than a third of respondents described their gender identity as nonbinary.[14] But how many people there are in any minority shouldn't matter to when and how we express our commitment to honoring their dignity.

One thing is certain, I am not the only one. And I will not be the only nonbinary individual who goes through medical training. I hope that pushing my colleagues to use my pronouns and generally asserting my identity will make it easier for colleagues and patients who follow. For my colleagues and patients, it is worth it. *I* am worth it. *They* are worth it. Their desire to avoid tangible dysphoric distress when people misgender them is valid. Colleagues' insisting upon their true self is not a burden at the expense of patients but is done with them—and with us. Self-advocacy can be patient advocacy. We are them, and they are all of us.

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